EARTHJUSTICE

Using TSCA Risk Management to Protect Public Health and Promote Environmental Justice

EPA recently announced its intent to "allow risk management actions on [the first 10 Toxic Substance Control Act risk evaluation] chemicals to move forward" despite the flaws in the prior administration's risk evaluations, and to "ensure environmental justice considerations are included within TSCA's process of identifying and addressing unreasonable risk."[1] We share both of those objectives, and this document provides a roadmap for achieving them through the TSCA risk management process. TSCA grants EPA broad authority to issue risk management rules that protect public health and the environment, address many of the acknowledged deficiencies in the first 10 risk evaluations, and realize President Biden's commitment to redressing environmental injustice. We urge EPA to follow the following steps, and to make full use of the authority described below, when developing those rules.

Step 1: Screening risk management options pursuant to Section 6(a)

- EPA should begin the risk management process by identifying risk management options that fully eliminate a chemical's unreasonable risks, consistent with TSCA Section 6(a)'s mandate to regulate chemicals "to the extent necessary so that the chemical substance … no longer presents such risk."[2] Pursuant to Section 6(a), only risk management options that eliminate unreasonable risk (on their own or in combination with other measures) may be considered.

- EPA should identify at least two risk management options that eliminate unreasonable risk for consideration pursuant to TSCA Section 6(c)(2), which requires EPA to evaluate the "proposed regulatory action and … 1 or more primary alternative regulatory actions."[3] EPA need not carry all possible risk management options forward for further analysis, and if there is one only option that eliminates unreasonable risk it should be the only one considered.

- Consistent with its past practice and the severe risks associated with the first 10 risk evaluation chemicals, EPA's starting point for risk management should be a ban on those chemicals (or, at a minimum, on their conditions of use that present unreasonable risk). Virtually all of the risk management rules that EPA has previously issued under TSCA involved whole or partial bans,[4] because such measures are effective, readily enforceable,

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[1] EPA Acting Assistant Admin. Michal Freedhoff, Prepared Remarks at ChemWatch: Key Regulatory Updates: Europe, Asia and the Americas 2021, March 25, 2021.

[2] 15 U.S.C. § 2605(a).

[3] 15 U.S.C. § 2605(c)(2)(A)(iv).

[4] *See, e.g.*, 43 Fed. Reg. 11,318 (Mar. 17, 1978) (banning the use of chlorofluorocarbons under certain uses); 44 Fed. Reg. 31,514 (May 31, 1979) (banning virtually all uses of polychlorinated biphenyls); 49 Fed. Reg. 36,855 (Sept. 20, 1984), 49 Fed. Reg. 24,668, (June 14, 1984), 49 Fed. Reg. 2,772 (Jan. 23, 1984) (banning certain uses of three metalworking fluids); 53 Fed. Reg. 10,206 (Mar. 29, 1988) (banning certain uses of hexavalent chromium); 54 Fed.

and offer the broadest protection of health and the environment. Other risk management approaches such as workplace exposure limits and labeling requirements provide less protection at greater administrative cost, and EPA lacks the resources to monitor and enforce those restrictions in the thousands of workplaces that use the first 10 risk evaluation chemicals or that manufacture or sell products containing those chemicals.[5] To be most effective and enforceable, bans should be targeted as far upstream as possible in the chemical manufacturing, import and distribution process. Such bans would not cause undue economic harm or disruption, because if a chemical has "critical or essential use[s] for which no technically and economically feasible safer alternative is available" or if a risk management rule "would significantly disrupt the national economy, national security, or critical infrastructure," TSCA Section 6(g) permits EPA to grant exemptions from the rule.[6]

Step 2: Analyzing risk management options pursuant to Section 6(c)(2)

- Once EPA has identified risk management options that eliminate unreasonable risk, at least one of which should be a whole or partial ban, EPA must evaluate those options pursuant to factors enumerated in Section 6(c)(2): the health and environmental effects of the chemical, magnitude of human and environmental exposure, benefits of the chemical, and the economic consequences of the risk management approach.[7] In considering these factors, EPA is not limited to the information and analyses contained in its risk evaluations. Instead, EPA must consider "reasonably available information" related to those factors,[8] which includes information "that EPA … can reasonably generate, obtain, and synthesize …."[9] As described below, several of the Section 6(c)(2) factors require EPA to look beyond the flaws in EPA's first 10 risk evaluations and to consider health effects, exposures, and regulatory benefits that EPA previously ignored.

- First, when considering "the effects of the chemical substance … on health and the magnitude of the exposure of human beings to the chemical substance"[10] and "the effects of the chemical substance … on the environment and the magnitude of the exposure of the environment to such substance,"[11] EPA is not confined to those impacts and exposures that were identified in EPA's risk evaluation. Instead, EPA has an independent obligation to consider chemical effects and exposures during the risk management

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Reg. 29,460 (July 12, 1989) (banning certain products containing, and new uses of, asbestos); 84 Fed. Reg. 11,420 (Mar. 27, 2019) (banning certain uses of methylene chloride).

[5] *See, e.g.*, EPA, *Proposed Rule: Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a)*, 81 Fed. Reg. 91,592, 91,607 (December 16, 2016) (acknowledging that "[e]nforcement under the other [non-ban] options would be much more difficult since the key requirements are directly placed on the large number of product users").

[6] 15 U.S.C. § 2605(g).

[7] *Id.* § 2605(c)(2).

[8] *Id.*

[9] 40 C.F.R. § 702.33.

[10] 15 U.S.C. § 2605(c)(2)(A)(i).

[11] *Id.* § 2605(c)(2)(A)(ii).

process, and should prepare supplemental analyses where needed to fill the gaps in the risk evaluations. These analyses include, but are not limited to:

- The magnitude of the exposure of humans and the environment from routes and pathways that were excluded from EPA's risk evaluations, including general population exposures from the air, drinking water, and disposal;[12]
- The magnitude of exposure of potentially exposed and susceptible subpopulations that were not considered in EPA's risk evaluations, including communities who neighbor facilities that release one or more of the first 10 chemicals;[13]
- The magnitude of exposure from foreseen combinations of exposure routes (i.e., dermal and inhalation) and combinations of uses (i.e., occupational and consumer uses);[14]
- The magnitude of likely exposure reductions given the efficacy, enforceability, and administrability associated with any particular risk management approach;
- Any health or environmental effects that were not evaluated in EPA's risk evaluations.

- Other information can be incorporated directly from the risk evaluations into the risk management process, without the need for additional analyses. For instance, in each of the first 10 risk evaluations, EPA calculated the chemical's risks to workers without the use of PPE, but the Trump Administration chose not to use those calculations when making its determinations of unreasonable risk. Instead, EPA unlawfully assumed that all workers across many conditions of use would be provided with and protected by respirators and chemical protective gloves. Further, in its TCE risk evaluation EPA identified fetal cardiac malformations as the most sensitive endpoint and calculated the risks for that endpoint, but the prior administration directed EPA staff not to use those analyses when making unreasonable risk determinations. EPA has since acknowledged that "political interference … compromised the integrity" of the TCE risk evaluation.[15]

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[12] When considering the risks associated with these exposure pathways, EPA "shall coordinate" its risk management actions with other EPA offices and should make findings that "it is in the public interest to protect against [unreasonable] risk by actions taken under [TSCA]." *Id.* § 2608(b).

[13] While potentially exposed or susceptible subpopulations will vary by chemical, they should also always include communities who face greater exposure due to their proximity to facilities that release the chemical or to chemical disposal sites where releases are ongoing; groups that have greater susceptibility due to pre-existing conditions, genetic polymorphisms, or socio-economic conditions that exacerbate the chemical's effects; groups whose life stage renders them more susceptible to the chemical's harms, such as pregnant women, children and infants, and fetuses; and workers, given their increased exposure from the chemical's manufacturing, occupational use, and disposal. *See Id.* § 2602(12).

[14] *Id.* § 2605(a) (requiring EPA to eliminate unreasonable risk from "any combination of" a chemical's conditions of use).

[15] *Inside EPA*, "Freedhoff Says 'Political Interference' Compromised TSCA TCE Evaluation" (Mar. 19, 2021), https://insideepa.com/daily-news/freedhoff-says-political-interference-compromised-tsca-tce-evaluation.

When evaluating risk management options under Section 6(c)(2), EPA must use the information that was before Trump Administration, but which that Administration discounted or ignored in the first 10 risk evaluations, including EPA's analyses of occupational risks without PPE and of TCE's effects on fetal cardiac development.

- Next, when considering "the costs and benefits of the proposed regulatory action and of … 1 or more primary regulatory alternative,"[16] EPA should not restrict its benefit calculations based on the limited information contained in the first 10 risk evaluations. Instead, consistent with EPA guidance,[17] past practice under other statutes,[18] and President Biden's executive order on *Modernizing Regulatory Review*,[19] EPA must consider all regulatory benefits from its risk management rules. For instance, if a ban on the manufacturing of a chemical confers health benefits on downstream users of the chemical substance or on the communities surrounding the facilities where the chemical is produced and used, EPA must consider those benefits when comparing risk management options, regardless of whether they were considered in the risk evaluation.

- When estimating benefits, EPA is also not limited to the assessment approaches used in the risk evaluations. While EPA's risk evaluations quantified the increased cancer risk associated with exposure to each chemical substance, they do not quantify the increased incidence of non-cancer effects, making it harder to calculate the full range of regulatory benefits from reducing chemical exposures. EPA can use available risk assessment methods to quantify non-cancer risks and benefits during the risk management process. In the event those benefits cannot be fully quantified, they should still be identified and considered.[20]

- President Biden has called on agencies to "take into account the distributional consequences of regulations"[21] and to "develop[] programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related and other cumulative impacts on disadvantaged communities."[22] These environmental justice policies are consistent with EPA's obligation to protect potentially

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[16] 15 U.S.C. § 2605(c)(2)(iv).

[17] EPA, *Guidelines for Preparing Economic Analyses* at 11-2 (2010), https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf.

[18] *See U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 591, 625 (D.C. Cir. 2016) (affirming EPA's authority, when conducting cost-benefit analyses under the Clean Air Act, to consider not only the direct benefits of regulating the listed pollutant but also "the potential co-benefits that limiting … emissions [of that pollutant] might have in lowering emissions of other … pollutants").

[19] Presidential Memorandum, *Modernizing Regulatory Review* § 2(b)(i), 86 Fed. Reg. 7223 (Jan. 26, 2021).

[20] *Id.*

[21] *Id.* § 2(b)(ii).

[22] Exec. Order No. 14,008, *Executive Order on Tackling the Climate Crisis at Home and Abroad* § 219, 86 Fed. Reg. 7619 (Jan. 27, 2021).

exposed or susceptible subpopulations under TSCA,[23] and they should be included in EPA's analysis of potential risk management options under Section 6(c)(2). In addition to EPA evaluating a chemical's impacts on the communities that suffer the greatest burdens, during the risk management process EPA should also conduct outreach to those communities and solicit their input on potential risk management actions.

Step 3: Selecting a risk management approach pursuant to Section 6(c)(2)(B)

- TSCA Section 6(c)(2)(B) grants EPA broad discretion to select the risk management approach that best protects public health, the environment, and impacted communities. While EPA "shall factor in" the Section 6(c)(2)(A) considerations "to the extent practicable," TSCA does not dictate how EPA should weigh those factors or instruct EPA to base its decisions on considerations of cost or cost-effectiveness.[24] President Biden's order on *Modernizing Regulatory Review* emphasizes the importance of accounting for "regulatory benefits that are difficult or impossible to quantify."[25] EPA should use its authority under TSCA to select health protective, equitable, and readily enforceable bans on unsafe chemicals, even if the full benefits of those bans cannot be quantified or monetized.

- This approach is consistent with the well-established hierarchy of controls for managing occupational risks, which prioritizes chemical elimination or substitution and permits the use of personal protective equipment only as a last resort.[26] The hierarchy of controls has been consistently applied and endorsed by OSHA, NIOSH, the American Conference of Governmental Industrial Hygienists and other experts in the fields of occupational hygiene, because it "leads to the implementation of inherently safer systems."[27] It constitutes the "best available science" for the management of occupational exposures and risks, and therefore it must be used when making any science-based decision under Section 6.[28]

- Finally, consistent with the Biden administration's goal of promoting a "sustainable" and "equitable economic future,"[29] EPA should use its risk management authority to promote safer alternatives to unreasonably risky chemicals. TSCA Section 6(c) requires EPA to consider the effects of its risk management rules on "technical innovation," and, when

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[23] 15 U.S.C. §§ 2602(12), 2605(a), 2605(b)(4).

[24] 15 U.S.C. § 2605(c)(2)(B).

[25] *Modernizing Regulatory Review* § 2(b)(i), note 18 *supra*.

[26] NIOSH, "Hierarchy of Controls," https://www.cdc.gov/niosh/topics/hierarchy/default.html (last updated Jan. 13, 2015).

[27] *Id.*

[28] *See* 15 U.S.C. § 2625(h) ("In carrying out sections [4, 5, and 6], to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.").

[29] *Executive Order on Tackling the Climate Crisis at Home and Abroad* §§ 101, 219, note 21 *supra.*

banning a chemical or a particular condition of use, to consider "whether *technically and economically feasible alternatives that benefit health or the environment* … will be reasonably available as a substitute."[30] For many of the first 10 risk evaluation chemicals, state agencies, non-profit organizations or EPA itself have already conducted analyses that confirm the existence of safer alternatives. When issuing risk management rules, EPA should recommend safer alternatives and should ensure that none of the first 10 risk evaluation chemicals are used as a substitute for any other (such as the replacement of methylene chloride with NMP or carbon tetrachloride). While EPA need not dictate particular substitutes through its rules, it can inform the public of the hazards associated with certain replacement chemicals and send a powerful market signal by indicating its intent to use TSCA and other EPA authority to evaluate and regulate those unsafe substitutes.

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[30] 15 U.S.C. §§ 2605(c)(2)(A)(iv)(I), 2605(c)(2)(C).